DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

2. This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

3. In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 3-13, drawn to a three component pharmaceutical composition wherein component A is a biguanide, component B is sulfonylurea and component C is a Glitazone.

Group II, claim(s) 14-27, drawn to a three component pharmaceutical composition wherein component A is a biguanide, component B is an ACE inhibitor and component C is aspirin.

Group III, claim(s) 28-42, drawn to a three component pharmaceutical composition wherein component A is a nitrate, component B is a platelet inhibitor and component C is an HMG-CoA inhibitor.

Group IV, claim(s) 43-56, drawn to a three component pharmaceutical composition wherein component A is a calcium channel blocker, component B is a beta-blocker and component C is a HMG-CoA inhibitor

Group V, claim(s) 57-72, drawn to a three component pharmaceutical composition wherein component A is a calcium channel blocker, component B is an angiotensin receptor antagonist and component C is an HMG-CoA inhibitor.

Claims 1 (and 2) are generic linking claims, whichever group Applicant elects will also encompass claims 1 (and 2).

4. The inventions listed as Groups I-V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

- The special technical feature for each group is not commonly shared. For example, the special technical feature of Group I requires that the three component pharmaceutical composition include biguanide, sulfonylurea and glitazone whereas the special technical feature of Group V requires that the composition include a calcium channel blocker, an angiotensin receptor and an HMG-CoA inhibitor. As these two Groups, as well as the other Groups of inventions, do not include any of the ingredients as the other, they therefore possess chemically distinct compounds that would necessarily exhibit different biochemical properties once introduced into a biological system. Therefore, the inventions or Groups of inventions lack unity.

5. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

6. The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

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8. Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Rejoinder Notice

9. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

10. In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be

amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Correction of Inventorship

11. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kyle A. Purdy whose telephone number is 571-270-3504. The examiner can normally be reached from 9AM to 5PM.

13. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisors, Ardin Marschel and Cecilia Tsang, can be reached on 571-272-0718 or 571-272-0562, respectively. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

14. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications

may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Kyle A. Purdy/
Examiner, Art Unit 4173

/Cecilia Tsang/
Supervisory Patent Examiner, Art Unit 4173